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Sildenafil for "blue babies". Such unlicensed drug use might be justified as last resort

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Undisclosed payments in research

Patients have the right to know motivations of researchers

EDITOR—Rao and Sant Cassia discussed the ethics of undisclosed payments to doctors recruiting patients in clinical trials.¹ For many years now the greater Glasgow community and primary care local research ethics committee has insisted that reference to doctors' payment is included in the patient information sheet that goes to all potential participants. I object to the payment being hidden behind such phrases as "your doctor's research fund will be paid," which a number of medical research ethics committees allow, and I note that the phrase "for the additional work involved" often appears.

Although the NHS and NHS Scotland are the remit of two different parliaments, cross border acceptance of approval by medical research ethics committees exists. Patients are also likely to see the NHS as a whole and the ethical principles of doctors and other healthcare professionals as not having regional variations. In the interests of equality (as well as informed consent) British guidelines need to be developed on this and other minimum requirements of information to be given to patients. This could include the amount of payment. My quick, non-random survey of my non-medical family and friends shows that the size of the payment and the potential overall income are underestimated.

Other types of personal gain exist for researchers that I also believe potential participants should know about—when the work forms part of the requirements for a degree. Some people who already have a professional qualification and who are using "their" patients in research do not always believe that it is necessary to inform patients

that they are registered for a degree for which this research is necessary. Such research may not always reach publication and may be designed as a learning experience rather than a complete piece of research. If patients are to be expected to take part in research for altruistic reasons they have a right to know what reasons motivate the people carrying out the research.

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¹ Rao JN, Sant Cassia LJ. Ethics of undisclosed payments to doctors recruiting patients in clinical trials. *BMJ* 2002;325:36-7. (6 July.)

Guidelines already exist

EDITOR—I write as a member and former chairman of the ethical issues committee of the Faculty of Pharmaceutical Medicine, a former medical director of the Association of the British Pharmaceutical Industry, and a member of two research ethics committees. Rao and Sant Cassia make several points that disregard the truth about phase IV clinical trials and do not differentiate between phase IV clinical trials and the safety assessment of marketed medicines, both of which are subject to strict guidelines.¹ These should be familiar to members of research ethics committees but are clearly unfamiliar to the authors of this paper.

Phase IV clinical trials, soon to be covered by the national legislation that follows the adoption of the European directive on clinical trials, are scientific projects already subject to ethical review. They are conducted in accordance with protocols submitted to medical and local research ethics committees as appropriate, and payments to be made are clearly included in the application for ethical review. Neither they nor safety assessment studies are designed solely to familiarise doctors with new and recently licensed medicines. They may well be required by the licensing authority to be conducted to establish a more robust safety database for a new medicine.

Rao and Sant Cassia seem to be ignorant of what they can already do about the concerns they express. This year's BMA annual meeting endorsed the need for the suggested fee for clinical research to be widely published so that research ethics committees, among others, can have up to date independent advice on an agreed

benchmark for payment to doctors taking part. Every phase IV study sponsored by a pharmaceutical company must be submitted to the appropriate research ethics committee(s), which can turn down an application if the payment is thought to be coercive. Studies into the safety assessment of marketed medicines do not need review by research ethics committees, but a BMA suggested payment exists for these, too. If a third party believes that a study is a marketing exercise masquerading as a research project or a safety assessment study, a complaint can be referred to the Prescription Medicine Code of Practice Authority and the company sanctioned if the complaint is upheld.

I agree that undisclosed payments to doctors recruiting patients in clinical trials would be unethical. However, payments must be disclosed to research ethics committees, which must therefore ensure that disclosure is complete and what is disclosed is acceptable.

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Sildenafil for "blue babies"

Such unlicensed drug use might be justified as last resort

EDITOR—We were disappointed to hear that a doctor in India has been criticised for treating pulmonary hypertension in three neonates (so called blue babies) with the phosphodiesterase type 5 inhibitor sildenafil (Viagra), a drug not licensed for this purpose.¹

Many drugs are widely and appropriately used outside their product licence.² Such prescribing practice is common in adult medicine, but is particularly prevalent in paediatrics because companies rarely undertake the work necessary to gain a licence for children. The decision to prescribe outwith a drug's licence should be supported by evidence of safety and potential benefit and, when possible, by a reasonable body of supporting professional opinion.

Of course, controlled clinical trials should be performed when possible to evaluate new treatments for specific indications. But these data are not always available, and then clinicians must make difficult decisions as to whether other information, such as efficacy and safety in other groups of

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patients, justifies unlicensed drug use. Subsequently, case reports should be published, facilitating scientific debate and informing the design of clinical trials.

Evidence is growing that sildenafil acts as a vasodilator in the pulmonary circulation and is effective in lowering pulmonary artery pressure in pulmonary arterial hypertension. This effect has been shown in adults with pulmonary hypertension and healthy volunteers with pulmonary hypertension induced by hypoxia.^{3,4} Intravenous sildenafil also normalised pulmonary artery pressure in an animal model of neonatal pulmonary hypertension.⁵

The evidence currently available is not sufficient generally to recommend the use of sildenafil in neonates with pulmonary hypertension. Assuming, however, that sildenafil was used as a last resort, after standard treatment, we believe that there are sufficient data to support the actions of this doctor. Perhaps the publicity that has arisen about this action will encourage further clinical research into the potential of inhibiting phosphodiesterase type 5 as a treatment for neonatal pulmonary hypertension, which may ultimately result in wider benefit to patients.

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Ethics, conscience, and science have to be balanced against limited resources

EDITOR—The unlicensed use of sildenafil (Viagra) by an Indian doctor to save "blue babies" has recently been the topic of a heated debate.¹ Before passing any judgment it is important to note that most neonatal nurseries in the developing countries cannot afford either to document or to treat persistent pulmonary hypertension in newborn infants by the currently accepted standards. Access to pulse oximetry and cardiac echocardiography is difficult, and very few units are equipped for ventilation and surfactant therapy.² Transfer to regional centres is almost impossible given the lack of neonatal transport services.

Advocating a theory of failure of conventional management before resorting to experimental treatments after informed consent is easy. It must, however, not be forgotten that the worldwide use of hyperventilation, muscle paralysis, bicarbonate infusion, and non-specific vasodilators such as

magnesium sulphate, prostacycline, glyceryl trinitrate, and sodium nitroprusside in the conventional management of persistent pulmonary hypertension in newborn infants is not based on evidence from any randomised controlled trials.³ The use of the most popular non-specific pulmonary vasodilator tolazoline has also been serendipitous, stemming from the original case report of persistence of the fetal circulation in 1969 rather than from controlled studies of its efficacy, kinetics, or safety.

The current expensive gold standard—using specific pulmonary vasodilator treatment and inhaled nitric oxide—is unlikely to be available or affordable in developing countries in the near future.³ Moreover, nitric oxide has also not proved to be the single magic bullet for persistent pulmonary hypertension in newborn infants. Nearly 20-30% of cases do not respond to nitric oxide, especially those with severe parenchymal lung disease (as in meconium aspiration and pneumonia) or pulmonary hypoplasia (as in congenital diaphragmatic hernia).³ The recent addition of adenosine, pentoxifylline, and dipyridamole as possible therapeutic options for persistent pulmonary hypertension in newborn infants is also based on case reports or series rather than randomised controlled trials.

Given the lack of resources, a conscientious doctor in a developing country may unsurprisingly resort to an experimental but potentially promising treatment in a desperate attempt to save a blue baby with possible persistent pulmonary hypertension when conventional treatments have failed.^{4,5} The issue of defining appropriate conventional treatments for persistent pulmonary hypertension in newborn infants in developing countries is extremely complex.

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Making the best of health advocates and interpreters

Telephone interpreting is not an acceptable solution

EDITOR—I agree with Adams's assertion that it is unacceptable to neglect to use interpreters with non-English speaking patients.¹ As she acknowledges, telephone interpreting is not ideal and should be used only if there is no other solution—for example, out of hours or in an emergency. Telephone interpreting

does not allow any checking on the quality of the translation unless you are using a telephone with a loudspeaker or two handsets.

In an ideal world interpreters would all be university trained and completely reliable, but good interpreters in most of the languages used by refugees are few, most being self taught. So keeping an eye on key words used, length of delivery, tone of voice, and other markers is crucially important for an adequate and complete interpretation.

Telephone interpreting is also impractical during examinations. It interrupts the flow and is not conducive to building rapport between doctor and patient. To most patients (and doctors) it seems somewhat artificial.

Since refugees were first assimilated in Glasgow in April 2000 our practice has provided medical care to refugees. Currently we have about 3200 refugees and asylum seekers registered with us. We arrange about 160-200 appointments weekly with (face to face) interpreters. We now have few (if any) difficulties in accessing interpreters, maybe because we refused any and all involvement with telephone interpreting services.

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- 1 Adams K. Making the best use of health advocates and interpreters. *BMJ* 2002;325(suppl):S9. (Career focus.) (13 July.)

Patient focused approach may help

EDITOR—The debate on making the best use of health advocates and interpreters can be broadened by considering the point of view of non-English speaking patients. In Adams's second scenario, in which a distressed non-English speaker wishes to terminate her pregnancy, the patient may prefer her general practitioner to use a telephone interpreter rather than talk face to face with an interpreter or a health advocate.

Some non-English speakers take great comfort from the anonymity of a telephone interpreter, particularly in small or closely knit ethnic communities. One of the factors contributing to the patient's distress in this scenario could be cultural or social pressures from within her community. If the patient is forced to talk to her general practitioner with another member of her community in the room, even if that person is a professional interpreter, she may feel unable to speak openly and honestly.

Another key issue is the number of non-English speakers who have health problems but never see a healthcare professional. The main reason is that non-English speakers are unable to access healthcare services by themselves. Either they must rely on friends or family members to help them or they must simply turn up and hope that a receptionist can put them in contact with an interpreter, health advocate, or bilingual member of staff.

At EITI we are talking to a number of primary care trusts and health authorities about a new service that allows non-English speakers far greater access to healthcare services. A series of telephone hotlines have

been set up, each with a particular language. Calls to the hotlines are answered by an interpreter who speaks the caller's language and a "talkback" officer who briefly determines the caller's need. The talkback officer has a conference call with the caller, the interpreter, and an English speaking member of staff at the caller's local general practice or hospital. Information can then be given to the caller over the telephone or an appointment can be made for a later date.

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Homosexual related legislation does not reduce suicidal intent in sexual minority groups

EDITOR—Bagley and D'Augelli contend that suicidal behaviour in bisexual, gay, and lesbian youth is an international problem associated with homophobic legislation.¹ Heretofore, no data existed to examine this. I recently found considerable variation in suicidal behaviour by sexual orientation cross culturally.² I re-examined the data to determine whether variations in suicidal behaviour are associated with national legislation on homosexual (a) adoption, (b) military service, (c) employment, and (d) marriage or domestic partnership.

A more detailed description of participants and methods can be found elsewhere.^{3,4} Four English speaking countries were selected from the intercontinental study²: Australia (n=185, 17.3% sexual minority groups), Canada (n=1178, 10.95% sexual minority groups), United Kingdom (n=116, 12.9% sexual minority groups), and United States (n=34 843, 13.41% sexual minority groups). Only countries with 15 or more participants in sexual minority groups were included to detect a proportional difference of 0.10, assuming a population proportion of $M=0.50$ (no difference), $\alpha=0.05$, and 70% power. National governments' positions on issues (a)-(d) above were scored 0 (no position), 1

(prohibited), and -1 (protected), with a range of 4 to -4.

The scoring was as follows:

- Australia -1: adoption 0, marriage or domestic partnerships 0, employment discrimination 0, military service -1
- Canada -4 (see Canadian Charter of Rights and Freedoms section 15(1), 1982; Human Rights Act 1996; judicial decisions): adoption -1, marriage -1, employment -1, and military service -1
- United Kingdom -2: adoption 0, marriage 0, employment -1, military service -1
- United States 2: adoption 0, marriage 1 (Public Law 104-199), employment 0, military service 1 (Department of Defense directive 1332.14, 28 January 1982).

The table shows suicide ideation and suicide attempts by each sexual orientation in country, with the odds ratio and 95% confidence interval for risk. The final two columns reflect the Pearson's correlation and its P value for the relation between the cumulative score for homosexual related legislation (index) and suicidal behaviour cross culturally. The percentage of homosexual suicide attempts were strong and significant but inversely related to the index ($r=-0.952$, $P<0.05$). The index was not significantly associated with other variables of suicidal behaviour.

In contrast to Bagley and D'Augelli's public policy thesis,¹ I tested a social constructivist model that suggests cultural attitudes towards human sexuality mediate the relation between suicidal behaviour and sexual orientation.² The present study provides empirical evidence to refute the public policy model. Thus, changing cultural attitudes towards human sexuality seems to be a more effective target of intervention for the suicidal behaviour of bisexual, gay, and lesbian youth than direct challenges to public policy related to homosexuality.

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Iron deficiency is neglected in women's health

EDITOR—The data by Waalen et al show that 38% of menstruating women living in San Diego are iron deficient using the accepted cut-off point of $<20\%$ for transferrin saturation as an indicator of deficiency. These data support our hypothesis that haematological distributions contain a large proportion of iron deficient women.¹

By focusing on the mean haemoglobin distribution, Waalen et al lose sight of a fundamental part of our work: why should women have lower reference limits for haemoglobin and serum ferritin concentrations than men? Our hypothesis for this was that a significant number of women are iron deficient. Mean values mask anomalies in distribution and are inappropriate to evaluate the issues we have raised. Since women menstruate, men would be expected to have higher mean haemoglobin concentrations because they can attain higher upper limits, so the 10g/l difference found by Waalen et al was not unexpected.

A similar situation occurs in menstruating but not in non-menstruating non-human primates.³ To support their case Waalen et al cite one menstruating non-human primate example—unfortunately this paper included data from infants, adolescents, and female animals half the age of the males, and it is therefore unreliable.⁴ Data analysis of a sex difference with age is more complex than simply presenting mean values from uncontrolled populations.

Close inspection of the ferritin data in part C of Waalen et al's study shows a large number of women "falling off" the lower end of the distribution. The haemoglobin difference between the sexes was of the range 15-20 g/l, which represents a significant proportion (39%) of the female distribution having a serum ferritin concentration below the lowest male value. In part B, the transferrin saturation data for 26-55 year old menstruating women show a significant difference in haemoglobin concentration of 15-25 g/l with a transferrin saturation below 20%, the accepted cut-off point for iron deficiency. In postmenopausal women (part D) 29% were affected. Ten per cent were classified as normal (haemoglobin concentration $>120\text{g/l}$) but were clearly iron deficient on the basis of having transferrin saturations $<10\%$.

Iron deficiency is a significant and seemingly neglected factor in women's health. Why should the lower reference level be sex dependent? What compelling evidence is there to support this apparent anomaly? In

Percentage of people with suicidal ideation and who attempted suicide, by sexual orientation and country, with national index scores for legislative policies on homosexuality, Pearson product moment correlation across countries, and associated probabilities

	Australia	Canada	United Kingdom	United States	r	P value
Legislation scores	-1	-4	-2	2	—	—
Suicidal ideation:						
Homosexual	28.1	28.5	18.8	25.3	-0.102	0.898
Heterosexual	24.2	14.9	18.0	13.8	-0.096	0.904
OR (95% CI)	1.23 (0.52 to 2.88)	1.05 (0.27 to 4.08)	2.28 (1.50 to 3.45)	2.13 (1.98 to 2.29)	0.564	0.436
Suicide attempts:						
Homosexual	12.5	13.1	12.5	10.3	-0.952	0.048*
Heterosexual	7.2	4.8	7.0	4.8	-0.105	0.895
OR (95% CI)	1.84 (0.55 to 6.21)	1.90 (0.36 to 0.07)	3.00 (1.68 to 5.38)	2.28 (2.05 to 2.54)	0.099	0.901

* $P<0.05$.

this context men are non-menstruating women, haematologically speaking.

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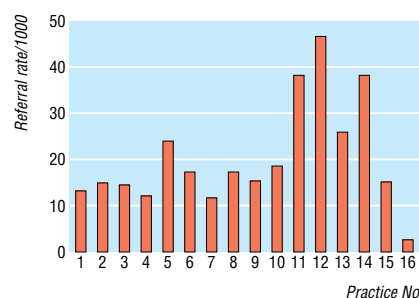
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Guidelines partly explain differences in referral rates

EDITOR—Forrest et al provide a useful insight into the variation in specialty referral rates between the United Kingdom and the United States.¹ However, their assertion that, given the low referral rates in the United Kingdom relative to the United States, referral guidelines are unlikely to dramatically enhance the capacity of specialties by decreasing demand is both a non sequitur and probably untrue.

We studied the referral rates for dermatology across the 16 practices in a primary care group with a comparatively uniform population mix. We found variations ranging from 2 per 1000 practice population to 47 per 1000 (figure), and the dermatologists thought that around 60% of referrals were for conditions that should be easily manageable by general practitioners with access to the right information. The practice with the lowest referral rate had a clinical assistant in dermatology and had modified its referral process so that all patients were referred through her.



Referral rates for dermatology to three trusts by 16 practices in primary care group

We found similar variability in orthopaedics and cardiology.

Referral rates can be reduced in many ways. The aim should be for the right patients to have access to the right level of skill at the right time without necessarily going to a hospital. The means to achieve this include better education, more community based expertise, mature clinical networks, and better use of technology such as clinical decision support (including referral guidelines) and telemedicine. There is plenty of room for improvement.

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Tailored exercise is key to preventing falls

EDITOR—The role of exercise in effectively preventing falls has had a mixed press. Profound conclusions have been drawn from research studies with severe limitations, including non-selection of those who had had falls, brief intervention periods, and exercise of insufficient intensity to stimulate improvement. Many were alarmed by a trial in which those who had falls fell more often after being encouraged to walk—if the authors had prescribed the balance, gait, and strength exercises used in New Zealand before walking, this unfortunate outcome could have been avoided.^{1,2} Today, scepticism about the true impact of exercise still remains among professionals and decision makers in the United Kingdom.

The study by Day et al is a welcome addition to the literature countering this alarmist view.³ In the United Kingdom the soon to be published falls management exercise (FaME) trial by Skelton et al found that in women aged over 65 with a history of falls who participated in prolonged specific group exercise, falls decreased by 60% and injuries due to falls by 75%. Prescribed exercises included those used by Campbell et al, as well as dynamic endurance, balance training, floor exercise, and coping strategies after a fall.² An accredited training course is now available nationally which covers the specific exercises used (see details below).

To test these study findings outside the research environment we set up a falls and injury prevention exercise service for people who had had falls and were living in the community (average age 81 years) in London in January 2000. Participants showed significant improvement in several known functional risk factors for falls and injuries, in addition to significantly increased scores in the SF36 domains of social contact, mental health, and change in health. Improvement in functional capacity is directly relevant to quality of life. As one participant said: "I can walk upstairs now. I

haven't been able to walk upstairs for four years. I do my exercises every day at home. I know it's doing me good."

Primary care trusts and social services departments are under pressure to promote the independence of their older residents. They would do well not to overlook the broad impact of tailored exercise in this area.

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Details of the postural stability training module can be obtained from East Midlands and Pennine Training (tel 0116 229 5512). It was developed by S Dinan and D A Skelton with a national advisory group and was funded by the Department of Health.

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Being difficult is not necessarily a bad thing

EDITOR—The tenor of King's article on dealing with difficult doctors is that being difficult is a bad thing.¹ I have two role models, one fictional and one real—Jesus Christ and the little boy who suggested that the emperor was wearing no clothes. They were both probably thought of as being difficult.

George Bernard Shaw said: "The reasonable man adapts himself to the world: the unreasonable one persists in trying to adapt the world to himself. Therefore all progress depends on the unreasonable man."²

The NHS needs more difficult or unreasonable doctors, not fewer.

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